GenePOC's Investment in Small Molecular Diagnostic Panels Validated by Medicare Decision, Company Says

Oct 23, 2018

NEW YORK (GenomeWeb) – In line with a recent coverage decision from Palmetto GBA concluding that large syndromic molecular diagnostic panels may not always be medically justifiable, molecular diagnostics manufacturer GenePOC is investing in the development of small syndromic PCR-based panels. The Canadian firm will now push forward on panels with around five targets beginning with tests for carbapenem-resistant enterobacteriaceae (CREs) and gastrointestinal pathogens.

The firm expects that microbiology labs will be swayed to adopt its existing menu by the anticipated future panels, and indeed, that has been the case for a lab in Florida that recently adopted the system.

GenePOC has developed a molecular diagnostics system called Revogene that can perform rapid real-time PCR-based testing. The instrument uses centrifugal microfluidics and consumable cartridges, called PIEs, that are capable of running tests with as many as 12 targets.

So far, GenePOC has pursued single-plex tests, receiving both US Food and Drug Administration clearance and Health Canada approval for a Group B Strep assay and a test for the toxin B gene of *Clostridium difficile* in the last year or so.

Although the firm's long-term goals have always included the development of small syndromic panels on Revogene, GenePOC is reenergized by the recent local coverage decision from Palmetto regarding respiratory panels that denies coverage for those containing more than six targets.

"The Palmetto decision validates the vision and the strategy that [GenePOC] had from the very beginning," Mike Blitz, the firm's vice-president of sales and marketing, said in an interview.

GenePOC is still finalizing products in what it refers to as a "minimum menu," Blitz said, including single-plex tests for *C. diff*, Group B Strep, and Group A Strep.

But it is also currently developing small panels for CRE bacteria and GI pathogens, with plans for others down the road, Blitz said. The tests are referred to as SMRT panels, which stands for specific, medically appropriate, reimbursement appropriate. The tests are being developed to have quick turnaround times.

"We are going into the panels to take the technology to the next step," he said, noting that the CRE panel, in particular, will "have tremendous clinical relevance in today's marketplace."

Small panels are not entirely new. For example, back in 2015 when large multiplex panels were really taking off, BD declared an intention to focus on making smaller multiplex panels in order to allow labs and clinicians more control over test utilization.

BD has continued to develop a line of multiplex syndromic solutions, each with only a handful of targets. In the women's health domain it makes a three-target STI test covering chlamydia, gonorrhea, and trichomonas, as well as a three-target bacterial vaginosis test. BD has also developed a five-target CRE test, and enteric panels for four common and four less common bacteria, as well as for three common GI parasites. BD also has a panel for five common enteric viruses that is under FDA review.

The difference between the two product lines may be in test volume, as GenePOC's is designed for lower-throughput testing. The Revogene platform runs eight samples in about 70 minutes, while BD's syndromic solutions run on the BD Max system that performs testing on 24 samples in three hours.

A recent head-to-head analysis of the firms' *C. diff* testing, performed at Johns Hopkins University and presented at the American Society of Microbiology Microbe meeting, showed BD's and GenePOC's assays to be comparable in terms of specificity and sensitivity.

GenePOC also believes that its system can be used "near patient," in small hospitals or in hospital wards. As such, it would be in the same competitive space as point-of-care and near-patient molecular systems like the Roche Liat, Abbott Alere i, and Cepheid GeneXpert Xpress, each of which runs only one or two targets and samples at a time. On the other hand, the BioFire FilmArray runs potentially near patients, but it remains to be seen whether the Palmetto coverage decision will impact uptake of its syndromic tests with around two dozen targets.

One early adopter of GenePOC noted in an interview that it was both the features of the single-plex tests and the promise of the multiplex panels that led her lab to adopt the Revogene.

Joanne Scuderi supervises the microbiology lab at Jupiter Medical Center in the North Palm Beach, Florida area. Her lab serves the community medical center's 250-bed hospital and affiliated physician offices. It runs approximately 3,500 samples for culture, rapid testing, and molecular testing per month, she said.

"The fact that GenePOC is expanding their menu was a big influence on my adoption of the system," Scuderi said. "We will definitely be looking into these panels in the future," she added.

The lab currently uses GenePOC for 90-100 *C. diff* tests each month. The GBS volume is much lower — about five per year — but Scuderi said the lab will be getting the medical center's marketing department involved in order to reach out to physician OB/Gyn offices in the area.

For *C. diff* testing, Scuderi said her lab had previously used Meridian Bioscience's Illumigene testing system. The lab decided to switch, she said, because GenePOC offers more automation, less pipetting and less steps, a printout of patient results, and a closed system with less chance of amplicon contamination.

Scuderi said the lab particularly appreciates that the GenePOC system is more automated and provides individual reports of each patient test result. If there were any improvements to be made, she would like to see an even faster turnaround time without compromising the sensitivity and specificity of the test, she said.

In terms of panel tests, the CRE test is in clinical trials now, and the GI panel is in development. "After GI, we'll either do respiratory or STDs, based on our market research," Blitz said. The STD panel, for example, may include CT/NG as well as Trichomonas and *Mycoplasma genitalium* with resistance testing, Blitz said. "There really isn't anybody who can do a six- or seven-target sexual health test the way that we can," he said.

Blitz declined to provide uptake data for the current menu but noted that the firm is having success by targeting competitors over which it can demonstrate clear performance or workflow advantages. The cost of the instrument and consumables also depends on volume and menu, he said, but it is "reasonably priced," he said.

GenePOC works with distributors in Europe and Canada, and with Cardinal Health for distribution in the US. "We fit a niche for them that they want to try to get into, which is multiplexing molecular diagnostics," Blitz said, adding that Cardinal selected GenePOC in part for its menu under development.

The firm is also working on an "early call" function for the Revogene, since real-time PCR can provide positive results in as little as 45 minutes, Blitz said. This may be provided as a software upgrade in the future pending FDA clearance. "We will be introducing the early call with our Strep A test, which should be coming out in the first part of next year," he said.

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